



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request (30-Day FRN); Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on July 16, 2012 (FR 77, 41791) and allowed 60-days for public comment. One public comment was received and a response was sent. The comment referenced alternative research that is unrelated to cancer screening. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Christine D. Berg, Chief, Early Detection Research Group,

National Cancer Institute, NIH, EPN Building, Room 3100, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301–496–8544 or e-mail your request, including your address to: bergc@mail.nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

PROPOSED COLLECTION: Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO), OMB No: 0925–0407, Expiration Date 9/30/2014, Revision, National Cancer Center (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This trial was designed to determine if screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 255,700 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then through 2014. During the first approval period a pilot study was conducted to evaluate recruitment methods and data collection procedures. Recruitment was completed in 2001, screening was completed in 2006, and data collection continues through 2016. When participants enrolled in the trial they agreed to be followed for at least 13 years from the time of enrollment. In 2011, participants were re-consented for at least an additional five years of follow-up. The current number of respondents is limited to the approximately 94,000 participants being actively followed up. This is down from the initial total. The reports on screening and prostate, lung, colorectal and ovarian cancer mortality based on this trial have been published in peer review medical journals. The additional follow-up

will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 31,813.

Estimates of Annualized Burden Hours					
Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hrs)	Total Burden Hours
Male and Female Participants	ASU	94,000	1	5/60	7,833
	Script for ASU Non-response	3,760	1	5/60	313
	HSQ	2,000	1	5/60	167
	MUQ	94,000	1	15/60	23,500
Total					31,813

Dated: October 5, 2012

Vivian Horovitch-Kelley

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NCI, NIH

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